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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,100	09/10/2003	Paul Albert Sagel	9031	4328
27752 7590 07/13/2006			EXAMINER	
	TER & GAMBLE CO	ROBERTS	ROBERTS, LEZAH	
INTELLECTUAL PROPERTY DIVISION WINTON HILL BUSINESS CENTER - BOX 161 6110 CENTER HILL AVENUE			ART UNIT	PAPER NUMBER
			1614	
CINCINNAT	I, OH 45224		DATE MAILED: 07/13/200	6

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)			
Office Action Summary		10/659,100	SAGEL ET AL.			
		Examiner	Art Unit			
		Lezah W. Roberts	1614			
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SH WHIC - Exter after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DANSIONS of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. It period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status						
1)⊠	Responsive to communication(s) filed on April	<u>27, 2006</u> .				
2a)[☐	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.					
3)						
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Dispositi	on of Claims					
5)□ 6)⊠ 7)⊠	Claim(s) <u>6-10</u> is/are pending in the application.  4a) Of the above claim(s) is/are withdraw Claim(s) is/are allowed.  Claim(s) <u>6-10</u> is/are rejected.  Claim(s) <u>8</u> is/are objected to.  Claim(s) are subject to restriction and/or	vn from consideration.				
Applicati	ion Papers					
9)□ 10)⊠	The specification is objected to by the Examine The drawing(s) filed on <u>March 2, 2004</u> is/are: a Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Ex	(a) accepted or $(b)$ objected to drawing(s) be held in abeyance. Section is required if the drawing(s) is ob	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).			
Priority (	under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
2) Notice	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail D	ate			
	3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date 20 Jun 2005.  5) Notice of Informal Patent Application (PTO-152)  6) Other:					

### **DETAILED ACTION**

## Response to Restrictions

Claims 1-5 and 11-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 27, 2006.

# **Drawings**

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "630" and "636" have both been used to designate void spaces, holes or apertures. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

#### **Claims**

### **Claim Objections**

Claim 8 is objected to because of the following informalities: the term "polyvinylpyrolidone" should read "polyvinylpyrrolidone". Appropriate correction is required.

#### Claim Rejections - 35 USC § 102 - Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 6, 8 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Leaderman (US 2002/0061329).

Leaderman teaches wound dressings for the oral cavity that may also be used to whiten teeth. The dressing can be in the form of a sheet impregnated by gel (page 1, paragraph 0002). Water hydratable polymers used to make the gels include vinyl polymers, also known as substituted polyethylenes. The polymers include polyvinyl, pyrrolidone and polyvinyl alcohols (paragraph 0028), encompassing claim 8. Gels can be lyophilized to provide a stable powder, from which gels can be reconstituted at the

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time of use, for use directly on dry sheets, foam or films, to deliver a dosage of the gel to the intended site of application, such as in the oral cavity. The whitening agents used to make whitening strips include hydrogen peroxide (page 5, paragraph 0057-0058). The invention also comprises a carrier for the gel formulation, such as gauze, sponge or other sheet that can become impregnated with the gel formulation. The dressing material in accordance with preferred embodiments of the invention can include porous, non porous, or micro porous polyesters, cottons (gauze, may be made of cotton: cotton fiber, once processed to remove seeds and traces of wax; protein; etc., consists of nearly pure cellulose, according to Wikipedia.com, encompassing claim 10), papers, foams (open and closed cell), woven and non-woven fabrics, polyurethanes, polyether block amides, ethylene methacrylic acids or polyethylenes. The reference anticipates the instant claims insofar as it teaches gel films comprising a whitening agent, which coats a mesh and at least partially fills said mesh.

2) Claims 6 and 8-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Chen (US 2002/0141950).

Chen teaches whitening compositions comprising a whitening agent and polyvinylpyrrolidone (paragraph 0054). The composition may be placed on a strip and delivered to the teeth. Whitening agents include hydrogen peroxide (paragraph 0052). The strip may be made from materials such as polymers, natural and synthetic wovens, non-wovens, foil, paper, rubber, and combinations thereof. It may be concluded the woven and non-woven materials have a mesh structure. In its raw form,

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polyvinylpyrrolidone is a white powder. In order to form a gel useful in dental bleach, a liquid component must be added to it. In some preferred embodiments of the invention, suitable liquid components of the gel include water, glycerin, propylene glycol, liquid polyethylene glycol, liquid propylene glycol, ethanol, and other suitable liquid components. Any of the liquid components can be used singly or in combination (paragraph 0059), encompassing claim 9. The whitening composition is either applied or coated onto the strip of material (paragraph 0085), which meets the requirement of the composition being a film in the instant claims. The material may be any type of polymer that meets the required flexural rigidity and is compatible with tooth whitening actives, such as peroxide. The material may comprise a single polymer or mixtures of polymers. Suitable polymers include, but are not limited to, polyethylene, ethylvinylacetate, ethylvinyl alcohol, and combinations thereof. Preferably, the material is polyethylene. The strip of material is generally less than about 1 mm thick, preferably less than about 0.05 mm thick, and more preferably from about 0.001 to about 0.03 mm thick. A polyethylene strip of material is preferably less than about 0.1 mm thick and more preferably from about 0.005 to about 0.02 mm thick (paragraph 0092). If the material was woven or non-woven and the material comprised of one layer, it may be conclude the fibers have a diameter of 1 to 200 microns. The reference anticipates the instant claims insofar as it teaches gel films comprising a whitening agent, which coats a mesh and at least partially fills said mesh.

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### Claim Rejections - 35 USC § 103 - Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen (US 2002/0141950) in view of Ruben (US 6,146,655).

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Chen teaches whitening compositions comprising a whitening agent and polyvinylpyrrolidone (paragraph 0054). The composition may be placed on a strip and delivered to the teeth. The strip of material is generally less than about 1 mm thick, preferably less than about 0.05 mm thick, and more preferably from about 0.001 to about 0.03 mm thick. A polyethylene strip of material is preferably less than about 0.1 mm thick and more preferably from about 0.005 to about 0.02 mm thick (paragraph 0092). The reference differs from the instant claims insofar as it does not teach the diameter of the fibers to be 1 to 200 microns.

Ruben teaches oral bandages and drug delivery systems. The systems are gel/fiber compositions wherein the fiber is used as reinforcement to the gel. The fibers have an individual length of at least 3 mm, and preferably in the range of from about 2 mm to about 4 mm, to obtain the desired reinforcement effect. There should be at least one order of magnitude difference between the diameter and length of the fibers. It is concluded the fibers will have a diameter of at the 200 microns when the length of the fibers is 2 mm. After the kit is removed from the liquid, the tacky fiber-reinforced gel is removed from the package and envelope, and manually molded and positioned in place over a desired tissue surface in a patient's oral cavity. The reference differs from the instant claims insofar as it does not teach the fibers form a mesh and the compositions include a tooth-whitening agent.

It would have been obvious to one of ordinary skill in the art to have used the fibers in the strips of the primary reference motivated by the desire to use material that

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would reinforce the gel compositions when wet and placed in the mouth as taught by the secondary reference.

Claims 6-10 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts
Patent Examiner
Art Unit 1614

Frederick Krass
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